

For chemotherapy-induced anemia (CIA)
in metastatic patients with Hb < 10 g/dL



**Catch hemoglobin levels
before they fall too far**

Important Safety Information including **Boxed WARNINGS** for Aranesp® (darbepoetin alfa)

WARNING: ESAs Increase the Risk of Death, Myocardial Infarction, Stroke, Venous Thromboembolism, Thrombosis of Vascular Access, and Tumor Progression or Recurrence

Chronic Kidney Disease:

- In controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered erythropoiesis-stimulating agents (ESAs) to target a hemoglobin level of greater than 11 g/dL
- No trial has identified a hemoglobin target level, Aranesp® dose, or dosing strategy that does not increase these risks
- Use the lowest Aranesp® dose sufficient to reduce the need for red blood cell (RBC) transfusions

Cancer:

- ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies of patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.
- To decrease these risks, as well as the risk of serious cardiovascular and thromboembolic reactions, use the lowest dose needed to avoid RBC transfusions.
- Use ESAs only for anemia from myelosuppressive chemotherapy, and discontinue upon completion of a chemotherapy course.
- ESAs are not indicated for patients receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
- Prescribers and hospitals must enroll in the ESA APPRISE Oncology Program to prescribe or dispense Aranesp® to patients with cancer; to enroll, visit www.esa-apprise.com or call 1-866-284-8089 for assistance.

Do not use Aranesp® in patients with uncontrolled hypertension; control blood pressure prior to and during treatment.

Do not use Aranesp® in patients with pure red cell aplasia (PRCA) that begins after treatment with Aranesp® or other erythropoietin protein drugs. If severe anemia and low reticulocyte count develop during treatment, withhold Aranesp® and evaluate for PRCA.

Do not use Aranesp® in patients with history of serious allergic reactions to the product, which may include anaphylaxis, angioedema, bronchospasm, skin rash and urticaria. Immediately discontinue Aranesp® if such a reaction occurs.

Adverse reactions in ≥ 1% of patients treated with Aranesp® in clinical studies were abdominal pain, edema, and thrombovascular events.

* Data from an exploratory, pooled analysis performed on a subset of placebo-treated patients (N = 411) from 6 randomized darbepoetin alfa CIA trials. Patients had baseline Hb ≥ 10 g/dL and decline to Hb < 10 g/dL at least once during the study-treatment period. Kaplan-Meier (K-M) estimates were calculated for the incidence of patients with transfusions by Weeks 0, 3, 6, and 9 after Hb < 10 g/dL was reached. Seventy-two percent of patients had lung cancer.⁴
† Data from a randomized, double-blind, placebo-controlled trial of 314 anemic (Hb ≤ 11 g/dL) patients with lung cancer receiving platinum-containing chemotherapy. Patients received once-weekly treatment with either Aranesp® (2.25 mcg/kg) or placebo, administered by subcutaneous injection, for up to 12 weeks. Per the pivotal trial protocol, doses were withheld if Hb exceeded 14 g/dL for women or 15 g/dL for men.²

Please see accompanying Aranesp® full prescribing information, including **Boxed WARNINGS** and Medication Guide.



Reduce RBC transfusions and achieve a gradual and steady Hb rise with Aranesp®¹⁻³

- In untreated patients whose Hb fell below 10 g/dL, 1 in 3 required an RBC transfusion within 6 weeks*⁴
- Aranesp® significantly reduced the need for RBC transfusions by 48% compared to placebo^{1,2}
- Aranesp® can be synchronized with the majority of chemotherapy regimens, including Q3W⁵

Aranesp® (darbepoetin alfa) Indication

Aranesp® is indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.

Limitations of Use:

Aranesp® has not been shown to improve quality of life, fatigue, or patient well-being.

Aranesp® is not indicated for use:

- In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
- In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
- As a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia.

 **Aranesp**[®]
darbepoetin alfa
Stabilize the fall

injection

Visit Aranesp.com for more information.

References: 1. Aranesp® (darbepoetin alfa) Prescribing Information, Amgen. 2. Vansteenkiste J, Pirker R, Massuti B, et al. *J Natl Cancer Inst.* 2002;94:1211-1220. 3. Canon JL, Vansteenkiste J, Bodoky G, et al. *J Natl Cancer Inst.* 2006;98:273-284. 4. Pirker R, Collins H, Legg J, et al. *J Clin Oncol.* 2011;29(suppl). Abstract e19637. 5. Data on file, Amgen; [Tandem Anti-cancer and Tumor Audit].



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